

# Comparison of Intracorporeal Knot-tying Suture (Polyglactin) and Titanium Endoclips in Laparoscopic Appendiceal Stump Closure: A Prospective Randomized Study

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**Background:** Laparoscopic appendectomy is a well-described surgical technique. However, concerns still exist regarding whether the closure of the appendiceal stump should be done with a clip, an endoloop, staples, or other techniques. Therefore, several modifications to the original technique with new materials have been introduced for appendiceal stump closure. The aim of this study was to compare intracorporeal (polyglactin) knot-tying suture with titanium endoclips in appendiceal stump closure during laparoscopic appendectomy.

**Methods:** The study was carried out as a prospective randomized clinical trial between April 2010 and February 2011. Patients with a presentation of appendicitis were included into the study. Two groups were defined—patients with the titanium endoclip and patients with the knot-tying (polyglactin) suture. The results in terms of operating time, complication rates, and hospital stay were analyzed.

**Results:** Sixty-one patients who underwent laparoscopic appendectomy were enrolled in the titanium endoclip group ( $n = 30$ ) or the knot-tying (polyglactin) suture group ( $n = 31$ ). No statistically significant differences were detected between the groups in terms of the distribution of age, sex percentage, appendix localization, and histopathologic diagnosis ( $P > 0.05$ ). One patient required a second operation on postoperative day 10 because of intraperitoneal abscess. The mean operative time for the endoclip group ( $41.27 \pm 12.2$  min) was shorter than that for the knot-tying group ( $62.81 \pm 15.4$  min) ( $P = 0.001$ ). No statistically significant differences were detected between the groups in terms of hospital stay, follow-up time, and preoperative and postoperative complications ( $P > 0.05$ ).

**Conclusions:** In laparoscopic appendectomy, using a titanium endoclip for optimizing and controlling the appendiceal stump closure is safe and is associated with shorter operation time. This also simplifies the procedure, so it can be a useful alternative to intracorporeal knot-tying for appendiceal stump closure.

**Key Words:** laparoscopy, appendectomy, knot-tying, endoclip  
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Appendicitis is a common condition generally affecting young, healthy people. It accounts for approximately

25% of surgical emergency admissions and >40% of all emergency laparotomies.<sup>1,2</sup> Laparoscopic appendectomy was first described by Semm<sup>3</sup> in 1983, and several studies have shown its advantage over open appendectomy, with better cosmesis, shorter hospital stays, less pain, and faster return to normal activities.<sup>4,5</sup> Moreover, it has proven to be a good diagnostic tool in suspected cases, especially for women.<sup>2,4</sup>

Although the surgical technique of laparoscopic appendectomy has been well established, concerns and controversy exists regarding the closure of the appendiceal stump, which is a key point in the procedure. Therefore, several modifications to the original technique with new materials have been introduced for optimizing and controlling the appendiceal stump closure, such as the endoloop, double endoloop, ultrasonically activated scalpel, instrument-assisted knotting, bipolar coagulation, slip-knot tying, metal clip, hem-o-lok polymeric clip, and linear endostaplers.<sup>6–14</sup> Controversies about the efficacy and safety of these novel materials still exist,<sup>7–16</sup> and the need to evaluate the various technical aspects of these novel materials through new research has become ever more important. In our institute, it is routine practice to use intracorporeal polyglactin knot-tying sutures for appendiceal stump closure during laparoscopic appendectomy. Titanium endoclips are the most commonly used clips in minimally invasive surgery because they are easy to use, safe and inexpensive<sup>17–20</sup>; however, they have not been used for appendiceal stump closure in laparoscopic appendectomy.

To date, no prospective randomized clinical study has been conducted to compare polyglactin suture with titanium endoclips. To clarify the results of using these 2 materials, we conducted a prospective randomized clinical trial to compare the use of intracorporeal polyglactin knot-tying suture with titanium endoclips in appendiceal stump closure during laparoscopic appendectomy.

## MATERIALS AND METHODS

The study was carried out as a prospective randomized clinical trial between April 2010 and February 2011 at Turgut Ozal Medical Center in Malatya, Turkey. Before starting the study, 2 groups were defined—patients with the titanium endoclip and patients with the knot-tying (polyglactin) suture. A power analysis was performed to determine the minimum sample size of both patient groups needed to achieve  $(1 - \beta) = 0.80$  power with a probability value of  $\alpha = 0.05$ ; this analysis suggested the sample size should be a minimum of 26 patients in each group. After we

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explained the details of the surgical procedure to all the participants and obtained written informed consent, patients were sent to the inpatient admission center for hospitalization and randomization. An officer not affiliated with the study consecutively randomized the patients to the knot-tying group or the endoclip group using patient admission numbers. All surgical procedures were performed by the first 2 authors, both being experienced in laparoscopic surgery. The study protocol was approved by the ethics committee and the institutional review board of the Medical Faculty of Inonu University (reference number 2010/33).

Seventy-three patients were evaluated as clinically suspicious of acute appendicitis. One patient who had plastron secondary to acute appendicitis, 3 patients who had perforated acute appendicitis, and 2 patients who did not accept the randomization were excluded. Six female patients were excluded because of ruptured hemorrhagic or simple ovarian cysts ( $n = 5$ ) and tubal abscess ( $n = 1$ ), as confirmed by a consultant gynecologist; the appendectomy was not performed for these patients. Thus, a total of 12 patients were excluded from the study. Finally, 30 patients in the endoclip group and 31 patients in the knot-tying group, totaling 61 patients who underwent laparoscopic appendectomy, were enrolled in the study.

### Surgical Technique

General anesthesia was applied for all patients. All patients received cefazolin 1g intravenously during the operation, and the skin was prepared with 10% povidone-iodine solution. The patients were placed on the table with the operating surgeon standing on their left side. After a pneumoperitoneum pressure of 14mm Hg was established by CO<sub>2</sub> with an insufflation needle placed just above the umbilicus, a 10-mm trocar was inserted in the umbilicus to introduce a 30-degree laparoscope. The peritoneal cavity was then inspected by a 30-degree scope. Once a diagnosis was obtained, if needed and under direct vision, an additional 10-mm trocar at the midline just 3 fingers above the pubic bone and a 5-mm trocar at the right upper quadrant near the subcostal region of the abdomen were inserted. All trocar positions can be seen in Figure 1. After the initial laparoscopic evaluation of the abdominal cavity, if the appendix was macroscopically inflamed, the patient was positioned head down and half-sided to the left. The appendicular mesentery was then grasped with endograspers, avoiding injury to the appendicular wall. A 5-mm LigaSure Atlas vessel-sealing instrument (Valleylab, Boulder, CO) was used for the mesoappendix dissection by the 5-mm trocar.

*For the knot-tying group*, after dissection of the mesoappendix, a no. 1 silk suture (Silk USP, Hunningen, Belgium) with flattened needle was introduced from the skin into the peritoneal cavity on the right fossa just at the level of the appendix and was taken out using a conventional and laparoscopic needle holder. The dissected, free appendix was stabilized by holding it in the loop, which was established by the silk suture, after which the appendix was hung on the posterior abdominal wall by tying the silk suture to the skin (Figs. 1, 2). The appendicular base was tied by a 2/0 polyglactin 910 (Vicryl Suture Ethicon Ltd, Edinburg, Great Britain) intracorporeal simple knot-tying suture. A second 2/0 polyglactin intracorporeal knot-tying suture was performed to tie the appendix a few millimeters away from the base knot, and a third intracorporeal knot-



FIGURE 1. Positions of the trocars.

tying suture was tied at about 5 mm from the second suture on the distal appendix (Fig. 3).

*For the titanium endoclip group*, after dissection of the mesoappendix, ligation of the appendicular base was done using 9- or 11-mm titanium endoclips (The Autosuture Endo Clip II ML or L); 2 endoclips were placed by a laparoscopic clip applicator in the proximal portion of the appendicular base, and a third clip was placed a few millimeters distally from the first 2 clips (if we had to use a 11-mm endoclip, we replaced the 10-mm trocar with a 12-mm one). The appendix was divided between the 2 proximal clips or between the knot-tying sutures using endoscopic scissors (Fig. 4). The appendix was evacuated



FIGURE 2. Hanging the appendix on the posterior abdomen by tying the silk suture to the skin.



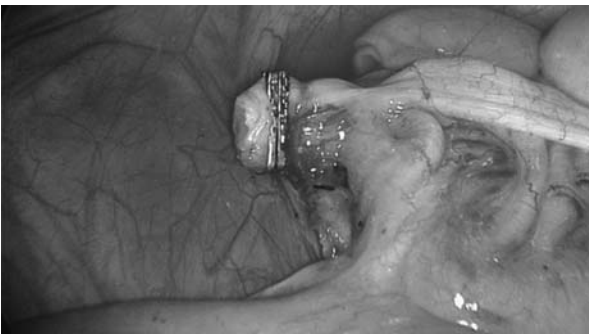
**FIGURE 3.** Ligation of the appendicular base by 2 polyglactin intracorporeal knot-tying sutures.

through the suprapubic 10-mm trocar; and regional peritoneal lavage with isotonic saline was performed.

When the appendix was normal and other pathologies explained the peritonitis, appendectomy was not performed. However, when there was no other surgical explanation for the symptoms, appendectomy was performed. In female patients with a normal appendix, a gynecologist was consulted to evaluate the screen and to give an opinion. When the procedure could not be completed thoroughly, it was converted to conventional open surgery. Appendix localization was defined as pelvic or retrocecal, and histopathologic diagnosis was confirmed to be acute suppurative, phlegmonous or gangrenous, perforated appendicitis or lymphoid hyperplasia and normal.

Prophylactic oral antibiotic therapy (cephalosporin) and anti-inflammatory therapy were given. The skin sutures were removed between postoperative days 10 and 13. Routine follow-up examinations were ordered for all patients for the first 3 months after surgery. Beyond 3 months, long-term follow-up of patients was monitored by phone calls every 3 months.

Patients' data including clinical history, physical examination, vital signs, white blood cell count, chest and abdominal x-ray, ultrasound findings, details of the procedure, operating time (included only the time required to perform the surgery from skin opening to skin closure), preoperative and postoperative complications, reasons for conversion to open surgery, length of hospital stay (days), mean follow-up duration (months), and postoperative



**FIGURE 4.** Ligation of the appendicular base by 2 titanium endoclips.

outcomes were evaluated and entered into the database for analysis.

### Statistical Analysis

The continuous variables are reported as means  $\pm$  SD, and categorical variables are reported by number and percentage. Normality for continuous variables was determined by the Shapiro-Wilk test, which revealed that the continuous variables showed normal distributions ( $P > 0.05$ ). The unpaired *t* test was used for comparison of variables between groups. For statistical evaluation of categorical variables, we used the Pearson  $\chi^2$  test and Fisher exact test as appropriate. *P* values of  $< 0.05$  were accepted as significant.

### RESULTS

In total, 61 patients underwent laparoscopic appendectomy. The endoclip group consisted of 30 patients (17 male, 13 female; mean age  $28.23 \pm 11.1$  y), and the knot-tying group consisted of 31 patients (19 male, 12 female; mean age  $29.35 \pm 8.2$  y). No statistically significant differences were detected between the groups in terms of the distribution of age, sex percentage, appendix localization, and histopathologic diagnosis ( $P > 0.05$ ). The demographic data of the 2 groups are displayed in Table 1.

Two patients in the endoclip group required the large-sized (11 mm) endoclip. Laparoscopy had to be converted to an open approach in 1 patient in the endoclip group and 2 patients in the knot-tying group because of severe inflammation and peritonitis due to perforated appendicitis with an abscess involving the base of the appendix (conversion rate is 3% and 3.2%, respectively). The number of preoperative and postoperative complications was 7 in the endoclip group and 6 in the knot-tying group. With the exception of 1 patient in the endoclip group, the others subsequently healed completely with conservative treatment (Table 2). One patient required a second operation on postoperative day 10 because of intraperitoneal abscess. The appendix stump base was observed to be intact; no slippage, dislodgement, or leakage of the clip and no ulceration of the appendix base were observed during the reoperation. In the endoclip group, 2 open titanium clips in the pelvic area of 1 patient were diagnosed by abdominal x-ray as the cause of abdominal pain on postoperative day 3. The mean operative time for the endoclip group ( $41.27 \pm 12.2$  min) was shorter than that for the knot-tying group ( $62.81 \pm 15.4$  min) ( $P = 0.001$ ). The length of hospital stay was  $2.07 \pm 1.2$  days in the endoclip group and  $2.06 \pm 0.9$  days in the knot-tying group. The follow-up time was  $180.3 \pm 82$  days for the endoclip group and  $175.1 \pm 84$  days for the intracorporeal knot-tying group. No statistically significant differences were detected between the groups in terms of hospital stay, follow-up time, and preoperative and postoperative complications ( $P > 0.05$ ). The clinical outcomes of the 2 groups are compared in Table 2.

### DISCUSSION

Laparoscopic appendectomy has gained popularity after the introduction of new devices such as sealing systems and the ultrasonic scalpel in the last 2 decades, despite its disadvantages over open surgery such as longer operation time, higher cost, and the need for technical apparatus and experience.<sup>4-6</sup> Appendiceal stump closure is the most controversial issue in the laparoscopic appendectomy

**TABLE 1.** The Demographic Data of the 2 Groups

|                                     | Titanium Endoclip Group | Intracorporeal Knot-tying Group | <i>P</i> |
|-------------------------------------|-------------------------|---------------------------------|----------|
| No. patients                        | 30                      | 31                              |          |
| Age (y)                             | 28.23 ± 11.1            | 29.35 ± 8.2                     | 0.962    |
| Women, n (%) / men, n (%)           | 17 (56.7) / 13 (43.3)   | 19 (61.3) / 12 (38.7)           | 0.714    |
| Histopathologic diagnosis           |                         |                                 | 0.654    |
| Acute suppurative                   | 17                      | 21                              |          |
| Phlegmonous or gangrenous           | 4                       | 2                               |          |
| Perforated                          | 2                       | 1                               |          |
| Lymphoid hyperplasia                | 4                       | 3                               |          |
| Normal                              | 3                       | 3                               |          |
| Enterobius vermicularis in appendix | 1                       | —                               |          |
| Appendix localization               |                         |                                 | 0.944    |
| Pelvic                              | 1                       | 1                               |          |
| Retrocecal                          | 3                       | 2                               |          |

procedure. Despite the fact that many authors have described several modifications with new materials for appendiceal stump closure, an optimal closure material has not yet been determined.<sup>7–16</sup> Moreover, most of these materials may prolong the operation time or increase cost, which may limit the popularity of laparoscopic appendectomy.<sup>6,8,9,21</sup> Recently, linear staplers and endoloops, both equally safe, have frequently been used as an alternative in the closure of the appendiceal stump during laparoscopy.

In routine cases, the intracorporeal knot-tying procedure requires 4 trocars. One holds the camera, 2 are for working to tie the suture, and the last is for holding and manipulating the appendix to be tied. If the fourth port is not used, the dissected appendix remains unsupported, and placing the knot precisely at the base becomes difficult. The percutaneous hanging technique was first introduced by Joshi et al<sup>22</sup> for laparoscopic appendectomy. This technique removed the need for the fourth trocar and reduced the operating time. We use this model with a minor modification, that is, without the use of an epidural, and thus we do not need a fourth trocar for stabilization. Although this hanging method is ergonomic and useful for intracorporeal knot-tying, the operation time is still longer than that for the endoclip procedure.

The titanium endoclip is made of a nonabsorbable metal material used routinely in surgery. Various studies, especially in laparoscopic cholecystectomy, have demonstrated that titanium endoclips can be used safely and efficiently. With the widespread use of the titanium endoclip in surgery, endoscopic procedures have been greatly facili-

tated, and operation times have been considerably shortened. Moreover, it can be applied easily and does not require advanced surgical skills on the part of surgeons.<sup>17–19,23,24</sup> The use of metal clips to close the appendicular stump was first described by Cristalli et al<sup>11</sup> in 1991. However, it has not gained general acceptance despite the increased popularity of laparoscopic appendectomy. Non-absorbable polymeric clips have lock systems that resemble the titanium endoclip, but they are expensive. Recently, some studies have compared the polymeric clip with the endoloop and stapler in appendiceal stump closure during laparoscopy and reported that the polymeric clip is safe, easy to use, and more cost effective.<sup>25–27</sup>

The results of our series suggest that titanium endoclips are safe and they shorten the operation time and simplify the procedure. Thus, the endoclip can be a useful alternative to intracorporeal knot-tying for appendiceal stump closure. Intracorporeal knot-tying techniques, in contrast to the endoclip, require hanging the appendix, which entails an added intervention and increases the operation time significantly. Despite the described advantages of the titanium endoclip in laparoscopic appendectomy, we must note the technical complication that 2 open endoclips were dropped into the patient's pelvic area intraoperatively in our study. While introducing the clip applier using the trocar with a clip loaded into the jaw during the appendiceal stump closure, the surgeon should pay attention to the space between the trocar and the camera view, which is a blind spot where the surgeon cannot see. It is thought that this loaded clip may have been dropped in this blind spot

**TABLE 2.** The Clinical Outcomes of the 2 Groups

|                                    | Titanium Endoclip Group (n = 31) | Intracorporeal Knot-tying Group (n = 30) | <i>P</i> |
|------------------------------------|----------------------------------|--|----------|
| Operative time (min)               | 41.27 ± 12.2                     | 62.81 ± 15.4                             | 0.001    |
| Perioperative complications, n (%) | 6 (20%)                          | 4 (13%)                                  | 0.679    |
| Subcutaneous or preperitoneal      | —                                | —  |          |
| Emphysema                          | 3                                | 2  |          |
| Dropped clip                       | 1                                | —  |          |
| Inferior epigastric artery injury  | 1                                | —  |          |
| Conversion                         | 1                                | 2  |          |
| Postoperative complications (n)    | 1                                | 3  | 0.939    |
| Intra-abdominal abscess            | 1                                | —  |          |
| Surgical site infections           | —                                | 1  |          |
| Abdominal pain                     | —                                | 1  |          |
| Reoperation                        | 1                                | —  |          |
| Hospital stay (d)                  | 2.07 ± 1.1                       | 2.06 ± 0.9                               | 0.994    |
| Follow-up time (d)                 | 180.3 ± 82                       | 175.1 ± 84                               | 0.818    |

and was not detected during surgery until we saw the patient's abdominal x-ray. After realizing this problem in the fifth patient, we made sure that the clip applicator was unloaded before each use. One concern is that a drawback of titanium endoclips may be abscess formation in the later period. There are no reports about abscess formation after appendectomy with endoclips; however, a few case reports of abscess formation associated with dropped metallic surgical clips after laparoscopic cholecystectomy have been reported, none of which has specified whether the clip was titanium.<sup>28,29</sup> Singh et al<sup>30</sup> reported an important study of 26 cases in which surgical metal clips were dropped during cholecystectomy, and none was associated with increased risk of abscess. They pointed out that dropped gallstones, rather than dropped metal clips, was the main cause of abscess formation in their study.

A second drawback of titanium endoclips is the question of migration, as some studies have presented case reports showing that metal clips used in cholecystectomy may migrate into the common bile duct. No prospective study or case report has discussed the migration of titanium endoclips used in laparoscopic appendectomy into the intestines, although some case reports have indicated the migration of the clip into the bile duct after cholecystectomy.<sup>31–33</sup> Despite the increasing number of cholecystectomies being performed annually, clip migration cases are still rare. The exact pathophysiology underlying the migration of endoclips into the bile duct is unknown. However postcholecystectomy clip migration into the bile duct has also been reported for absorbable clips. The most likely reason for migration is improper or erratic application of the clips, resulting in bile leakage. Secure and correct placement of the clips could help prevent this complication.<sup>31–34</sup>

Beldi et al<sup>35</sup> reported that 1 endoloop used in appendiceal stump closure is sufficient and safe. We used double intracorporeal knot-tying sutures and double titanium endoclips, and there were no differences in the complication rate or length of hospital stay between these groups. Our experience in all 61 cases revealed no increased risk of complications and leakage in laparoscopic appendiceal stump closure with intracorporeal knot-tying, but the operation time is significantly longer than that with endoclip closure because the intracorporeal knot-tying is not as easy as endoclip application and requires extensive laparoscopic training.

This is the first prospective randomized study comparing the use of endoclips with intracorporeal knot-tying suture in laparoscopic appendectomy. However, there is a limitation of this study in that the follow-up period was not enough to discuss long-term side effects of titanium endoclips such as migration. Data on clip migration reveal that such migration can occur at any time, but mostly occurs at a median of 2 years after cholecystectomy.<sup>33</sup> However, no information about clip migration in appendectomies is available to date.

Laparoscopic appendectomy is increasingly becoming a method of choice, especially in the treatment of female patients with acute appendicitis. Using titanium endoclips for optimizing and controlling the appendiceal stump closure is safe, it shortens the operation time, and also simplifies the procedure, so it can be a useful alternative to intracorporeal knot-tying for appendiceal stump closure. Further studies with long-term results will be useful for evaluating the adoption of titanium endoclips in laparoscopic appendectomy.

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